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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,037	12/31/2001	Avigdor Levanon	10793/44	8494

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,037	LEVANON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-13,153,154,156,157 and 164* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,5,13,153,154,156,157 and 164* is/are rejected.

7)☐ Claim(s) *2-4 and 6-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~11/12/2004~~ 7/14/05 KAC 11/8/05

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claims 14-152, 155 and 158-163 have been canceled. Claim 164 has been added. Claims 1-9, 11, 12, 153 and 157 have been amended. Claims 1-13, 153, 154, 156, 157 and 164 are pending and under consideration.

The sequence listing and CRF submitted April 19, 2005 are both objected to for assigning a different sequence identifier to the same sequence. SEQ ID NO:266 and 269 are identical both in the Sequence Listing and in the CRF.

Claim 164 is object to for using a different Sequence Identifier for the same sequence, YDYYPEE which is identical to SEQ ID NO:266.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Mosesson et al (WO 98/12318) or Muramatsu et al (Peptide Chemistry, 1995, Vol. 32, pp. 297-300) or Hubbell et al (US 2003/0064410) is maintained for reasons of record.

Mossesson et al disclose

(i) a peptide comprising the sequence HPAETEYESLYP (Registry No. 204975-91-7) wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-A-X, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, thus anticipating claim 1; and also anticipating claim 5, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-Ala, P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ser-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro;

(ii) a peptide comprising the sequence HPAETEYESLYPEDD (Registry No. 204975-94-0), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2; and also anticipating claim 5, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-Ala,

P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ser-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro-Glu-Asp-Asp, wherein m or n =2 for the final (A) group;

(iii) a peptide comprising the sequence AETEFESLYPEDD (Registry No. 204975-95-1), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(iv) a peptide comprising the sequence HPAEVEYEALYPEDD (Registry No. 204975-97-3), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, sulfo-Tyr, X-A-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2; and also anticipating claim 5, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-Ala, P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ala-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro-Glu-Asp-Asp, wherein m or n =2 for the final (A) group;

(v) a peptide comprising the sequence AETEYESLYPEDD (Registry No. 204975-96-2) wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, sulfo-Tyr, X-A-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(vi) a peptide comprising the sequence AEVEYEALYPEDD (Registry No. 204976-00-1 and Registry No. 204976-03-4) wherein the sequence comprises the instant W=Ala, P(first)=Glu, P(second)=Val-Glu, sulfo-Tyr, P(third)=Glu-Ala-Leu, sulfo-Tyr, P(fourth)=Pro-Glu-Asp-Asp, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(vii) a peptide comprising the sequence EALYPEDD (Registry No. 204976-02-3), wherein the sequence comprises W=0 by virtue of z=0, P=A-X-A, sulfo-Tyr, X-A-A, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2, thus fulfilling the specific embodiments of claim 1;

The disclosed peptides fulfill the specific embodiments of claims 1 with regard to being capable of binding to an antibody or an antigen-binding fragment thereof, because all peptides are thus capable.

Muramastsu et al disclose a peptide comprising the sequence FEEIPYYYLQ (Registry No. 165598-24-3), wherein the instant W=F, P=(A)n(A)mX, wherein (A)n is Glu-Glu, (A)m is Ile and X is Pro, wherein t=3 and (Y)t is sulfo-Tyr-sulfo-Tyr-sulfo-Tyr and wherein P=(A)n(A)m(X)u, wherein m=0 and u=1 and wherein n and u=1, A=L and X=Gln.

Hubbell et al disclose

(a) the peptide comprising the sequence VFVSSVVSS (Registry No. 491841-54-4), wherein W=Val, P=(A)n(A)m(X)u, wherein m=0 and n and u=1, wherein (A)n=Phe and (X)u=Val, wherein t=2 and (Y)2=sulfo-Ser-Sulfo-Ser, wherein u and m=2, and n=0, wherein P=(X)u(A)m(A)n is Val-Val-Ser-Ser. It is noted that the limitation of binding to an antibody or antigen binding fragment thereof comprising SEQ ID NO:8 is not applied to the entirety of the claims because of the broadest reasonable interpretation of the claims as set forth under the rejection under 112, second paragraph above. The sulfo-Tyr fulfills the specific embodiment of claim 2 drawn to a peptido conjugate as the sulfo-Ser moiety is a peptido conjugate. Mossesson et al disclose compositions comprising said peptides (page X, lines Y-Z) thus fulfilling the specific embodiment of claim 14. Claims 15 and 16 are included with this rejection because it is unclear what the epitome is binding to; and

(b) the peptide comprising the sequence GGYDYG (Registry No. 491841-60-2), wherein W=Gly, P=(A)n(A)m(X)u, wherein m and u=0 and (A)n=G, sulfo-Tyr, P=(A)n(A)m(X)u, wherein m and u=0 and (A)n=Asp.

The rejection of claims 1, 5 and 13 under 35 U.S.C. 102(b) as being anticipated by Leppanen et al (Journal of Biological Chemistry, 1999, Vol. 274, pp. 24838-24848)

Leppanen et al disclose the glycosulfopeptide-6 (GSP-6, page 24840, Figure 2) having the sequence GQATE-sulfo-Tyr-E-sulfo-Tyr-LD-sulfo-Tyr-DFLPETEPPEML having a sialyl Lewis carbohydrate motif on the Threonine of residue 57, thus fulfilling the specific embodiment of claim 13 specifying an additional post-translational modification. The disclosed peptide sequence fulfills the specific embodiments of claims 1 and 5 having W=Ala, X-A=Thr-Glu,

sulfo-Tyr, A=Glu, sulfo-Tyr, AA=Leu-Asp-sulfo-Tyr, AAX=Asp-Phe-Leu to anticipate claim 5, or W=Leu, A=Asp-sulfo-Tyr, A=Asp to anticipate claim 1.

The rejection of claim 1, 5, 153, 154, 156 and 157 under 35 U.S.C. 102(b) as being anticipated by Ward et al (Biochemistry, 1996, Vol. 35, pp. 4929-4938) is maintained for reasons of record. New claim 164 is also rejected for the same reasons of record.

Ward et al disclose an isolated epitome comprising amino acid sequence Tyr276 to Glu282 of GPIbalpha (lines 14-16 of abstract) wherein at least one tyrosine residue is sulfated, this peptide also metes the specific embodiment of claim 156 which specifies the sequence YDYYPEE; an isolated epitome comprising amino acid sequence Tyr276 to Glu282 and further comprising residues 283-285 (page 4935, first column, lines 15-21) because Ward et al disclose the peptide consisting of residues 1-282 of GPIbalpha (page 4934, first column, line 12). It would be inherent in the peptide of residues 1-282 of GPIbalpha that at least one of amino acids 276, 278 and 279 is sulfated because the peptide comprises the sequence YDYYPEE which was disclosed by Ward et al to be 90% sulfated on Tyr 278 and 279 and 50% sulfated on Tyr 282. Ward et al disclose the peptide of DEGDTDLYDYYPEEDTEGD (page 4930, first column, line 44) which fulfills the specific embodiments of claims 5 and 6 with (Y)r=0, because z=1, (W)z=Gly, P(first)=Asp-Thr-Asp as (A)n(X)u(A), P(second)=Leu as (A)n, wherein m and u=0, sulfo-Try, P(third) as (A)n=Asp, wherein m and u=0, t=2 and (Y)t=sulfo-Try-sulfo-Tyr, P(forth)=Pro-Glu-Glu-Asp as (X)u(A)n(A)m, wherein u and m=1 and n=2 and (X)u=Pro, (A)n=Glu and (A)m is Asp. Said epitome also fulfills the specific embodiment of claims 1-3 wherein z=0, P(first)=(A)n(X)u(A)m, wherein, n=u=m=1 and wherein (A)n=Asp, (X)u=Thr and (A)m=Asp; t=1 and (Y)t=sulfo-Try; and wherein P(second)=(A)m(A)n(X)u, wherein n and u are 0 and wherein (A)m is Asp.

Applicant argues that the references do not disclose that said epitopes is capable of being bound by a human antibody, wherein said human antibody comprises a first hypervariable region comprising SEQ ID NO:8. This has been considered but not found persuasive. The peptides

have the specific structural requirements of the claimed epitopes and therefore all would be "capable" of binding to an antibody comprising the hypervariable region of SEQ ID NO:8.

Claims 2-4 and 6-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth in the previous Office action are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
10/31/2005